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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,552	09/18/2001	Julian I. Schroeder	19452A-000210US	1470

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,552

Applicant(s)

SCHROEDER ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-14, filed November 7, 2003, is acknowledged. The traversal is on the ground(s) that PCT unity of invention rules require that all the claims be examined together, as all the claims relate to the discovery that farnesyltransferase is involved in the mechanism of regulating guard cells in plants, and that inhibiting farnesyltransferase renders plants more resistant to drought, which discovery is a special technical feature that makes a contribution over the prior art. The traversal is also on the ground(s) that a search of all of the claims would not be unduly burdensome.

This is not found persuasive because the claims are not directed to regulating guard cells in plants, or to inhibiting farnesyltransferase in plants in order to render the plants more resistant to drought. The claims are directed to plants comprising a recombinant expression cassette encoding a farnesyltransferase inhibitor, different methods of inhibiting farnesyltransferase in plants, and a composition comprising an inhibitor of farnesyltransferase. Accordingly, the technical feature linking the different groups of invention is farnesyltransferase inhibition. However, farnesyltransferase inhibitors, and farnesyltransferase inhibition in plants, was known in the art as exemplified by PATEL et al. (US Patent No. 5,444,087, issued 22 August 1995, Applicant's Search Report) and QIAN et al. (Plant cell, December 1996, Vol. 8, No. 12, pages 2381-2394, Applicant's Search Report), and therefore does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. This is also not found persuasive because while a search of the different groups of invention may overlap with respect to farnesyltransferase inhibition in plants, their searches are not coextensive,

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because the different groups require searches of different technical methods for the inhibition of farnesyltransferase.

Claims 1-14 are examined, and claims 15-24 are withdrawn from consideration. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a plant comprising an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor of unspecified structure and function, including an unspecified protein inhibitor, and to a method of inhibiting farnesyltransferase in a plant by transforming a plant with said expression cassette, including a method in which the inhibitor inhibits the farnesyltransferase alpha-subunit or the farnesyltransferase beta-subunit.

The specification indicates that nucleic acids encoding known peptide inhibitors of farnesyltransferase could be introduced into plants to inhibit farnesyltransferase, and that farnesyltransferase could also be inhibited in plants using a variety of other recombinant DNA techniques (pages 15-24). The specification does not, however, describe any particular method of

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inhibiting farnesyltransferase in a plant using any particular recombinant expression cassette.

The specification also does not describe or characterize any particular plant transformed with any particular recombinant expression cassette.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus, nor the structural features unique to the genus. The rejected claims are directed to plants comprising a broad genus of any nucleic acid sequence of unspecified structure and function encoding any protein whose expression would inhibit farnesyltransferase in a plant, yet the specification fails to describe even a single species falling within the scope of the claimed genus. The specification also fails to describe any specific structural features that are unique to nucleic acid sequences encoding a protein whose expression would inhibit farnesyltransferase in a plant.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are drawn to a plant comprising an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor of unspecified structure and function, including an unspecified protein inhibitor, and to a method of inhibiting farnesyltransferase in a plant by transforming a plant with said expression cassette, including a method in which the inhibitor inhibits the farnesyltransferase alpha-subunit or the farnesyltransferase beta-subunit.

The specification indicates that nucleic acids encoding known peptide inhibitors of farnesyltransferase could be introduced into plants to inhibit farnesyltransferase, and that farnesyltransferase could also be inhibited in plants using a variety of other recombinant DNA techniques (pages 15-24). Additionally, the specification discloses that *Arabidopsis* plants treated with the farnesyltransferase inhibitors alpha-hydroxyfarnesylphosphonic acid or manumycin exhibit increased sensitivity to ABA induced stomatal closure (page 27 and figure 1). The specification also discloses that *eral-2 Arabidopsis* mutants that lack farnesyltransferase also exhibit increased sensitivity to ABA induced stomatal closure, as well as reduced transpiration under drought conditions (pages 28-30 and figure 2). The specification does not, however, disclose any method of inhibiting farnesyltransferase in a plant that involves the use of a recombinant expression cassette.

The claimed invention is not enabled because the specification does not provide guidance with respect to the nature and identity of the farnesyltransferase inhibitors that would be encoded by the nucleic acid sequence of the expression cassette, or how to express the inhibitors in a manner that would confer a useful phenotype on a plant transformed therewith. Such guidance is necessary because the effect of expressing a nucleic acid encoding a farnesyltransferase inhibitor in a plant is unpredictable. The effect is unpredictable because expression methods must be specifically adapted in order to achieve a particular desired phenotype, as different levels of

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protein expression produce different phenotypes. The effect is also unpredictable because farnesyltransferase inhibition is dependent on inhibitor concentration and further varies between different types of farnesyltransferase inhibitors, and because compounds that inhibit farnesyltransferase in vitro may be unstable in vivo.

See for example Tamanoi, who teaches that the IC₅₀ for farnesyltransferase varies from 0.01 uM to 21 uM among 10 different types of farnesyltransferase inhibitors (Trends Biochem Sci 1993 Vol. 18, No. 9, pages 349-353, see page 350 Table I). See also Reiss et al., who teach that different species of peptide inhibitors also vary in the concentration at which they inhibit farnesyltransferase activity (Cell, 1990, Vol. 62, No. 1, pages 81-88, see page 85 Figures 9-11). Additionally, see Lerner et al., who teach that the development of CAAX tetrapeptides for use as anticancer drugs has required that CAAX tetrapeptides be chemically modified to prevent their proteolysis and increase their stability in vivo (Anticancer Drug Res 1997, Vol. 12, No. 4, pages 229-238, see page 231-232).

In the instant case it would require undue experimentation to make and use the claimed invention because Applicant has provided no guidance with respect to how to express any particular farnesyltransferase inhibitor at an effective concentration in a transgenic plant. Applicant has also provided no guidance with respect to which particular farnesyltransferase inhibitors would be stable and thus effective when expressed in a plant. Absent specific guidance with respect to which particular farnesyltransferase inhibitor to express in a plant and how to express it, one skilled in the art would have to resort to trial and error experimentation in order to identify and/or modify farnesyltransferase inhibitors that would have adequate stability when expressed in a plant cell, as well as to select and optimize an appropriate methodology for the expression of the identified inhibitors at an effective concentration.

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Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 20, 2004

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600